510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K123048

JAN 11 2013

Submitter

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Date Prepared:

December 19, 2012

Device name and classification:

- **Device Name:** Patient Monitor Models PM-2000A, PM-2000A+ & PM-2000A Pro
- **Regulatory Class:** Class II
- **Device Common Name:** Patient Physiological Monitor (with arrhythmia detection or alarms)

Classification:

Description	Classification	Product code
21 CFR 870.1025 Arrhythmia detector and alarm (Including ST-segment measurement and alarm)	II	MHX
21 CFR 870.2300 Cardiac monitor (including cardiotachoment and rate	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.2900 cable, transducer and electrode, patient, (including	II	DSA
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI

Regulatory Class: Class II

Predicate Device:

iM8, iM8A & iM8B Patient Monitor K113653 Manufacturer: EDAN Instruments

Device Description:

The Patient Monitor Models PM-2000A, PM-2000A+ & PM-2000A Pro can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time. The patient monitor supports software upgrade online and networking and build-in battery power is available for all the models.

The Patient Monitor Models PM-2000A, PM-2000A+ & PM-2000A Pro can monitor physiological parameters including SpO2, NIBP, ECG, RESP, TEMP, C02, IBP. The above is the maximum configuration; the user may select different monitoring parameters in according with specific requirements. The main difference between Patient Monitor models is the screen size as it is illustrated in the table below:

Product models	Size (LxWxH)	Screen size	Monitoring features
PM-2000A	320mmx150mmx265mm	10.1-Inch	ECG/RESP.SPO2, NIBP, TEMP, IBP, CO2
PM-2000A+		10.4-Inch	
PM-2000A Pro		12.1-Inch	

Intended Use:

Device Name: Patient Monitor Models PM-2000A, PM-2000A+ & PM-2000A Pro

The device monitors parameters such as ECG (3-lead or 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), and Expired C02.

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in a hospital environment and during patient transport inside a healthcare facility. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Contraindications:

It is not intended for use in a patient's home or residence, or when it has not been ordered by a physician.

Non Clinical Tests:

The following quality assurance and product safety measures were applied to the development of the Patient Monitor:

- Software Testing
- Hardware Testing
- Biocompatibility data for accessories
- Electrical Testing
- Safety Testing
- Environment Test
- Risk Analysis
- Final Validation

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device cleared under K113653. Both models use the same technology and manufacturing processes.

Substantially Equivalent Determination:

Verification and Validation testing was done on the Patient Monitor. This premarket notification submission demonstrates that the Patient Monitor Models PM-2000A, PM-2000A+ & PM-2000A Pro is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 11 2013

Advanced Instrumentation, Inc.
c/o Dr. Jorge Millan
601 West 20th Street
Hialeah, FL 33010

Re: K123048
Trade/Device Name: Patient monitor models pm-2000a, pm-2000a+, pm-2000a pro
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class II
Product Code: MHX, DXN, DRT, DSK, FLL, DQA, DSA, DSI
Dated: September 28, 2012
Received: October 17, 2012

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123048

Indications for Use

510(k) Number (if known):

Device Name:

Patient Monitor Models : PM-2000A, PM-2000A+ & PM-2000A Pro

Indications for Use:

The monitor monitors parameters such as ECG (3-lead or 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired C02.

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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123048